K023907
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Appendix A

Summary of Safety and Effectiveness

DEC 1 8 2002

General Provisions

The name of the device is:

Proprietary Name	Common or Usual Name
Cordis Maxi LD Large Diameter Balloon Dilatation Catheter	Esophageal Dilator

Name of Predicate Devices

The device is substantially equivalent to:

- Cordis Maxi LD Large Diameter Balloon Dilatation Catheter
- B. Braun IMPACT Balloon Dilatation Catheter

Classification

Class II

Performance Standards

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

Indications for Use

The intended use of the Cordis Maxi LD Large Diameter Balloon Dilatation Catheter is for the dilatation of strictures of the esophagus.

Device Description

The device is an over the wire balloon catheter, with a distal balloon and a proximal hub. The balloon features two radiopaque marker bands.

Biocompatibility

All materials used in the Cordis Maxi LD Large Diameter Balloon Dilatation Catheter are biocompatible.

Summary of Substantial Equivalence

The design, material, components, method of delivery, fundamental technology and intended use featured with the Cordis Maxi LD Large Diameter Balloon Dilatation Catheter are substantially equivalent to the predicate Cordis Maxi LD Large Diameter Balloon Dilatation Catheter (see 510(k) #K993720). In short, the subject device represents a line extension of the additional 22 & 25 mm balloon diameters to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2002

Ms. Donna Marshall
Regulatory Affairs Associate II
Cordis Corporation, a Johnson &
Johnson Company
7 Powder Horn Drive
WARREN NJ 07059

Re: K023907
Trade/Device Name: Cordis Maxi LD Large Diameter Balloon Dilatation Catheter, and Cordis MAXI LD PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR §876.5365
Regulation Name: Esophageal dilator
Regulatory Class: II
Product Code: 78 KNQ
Dated: November 23, 2002
Received: November 25, 2002

Dear Ms. Marshall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

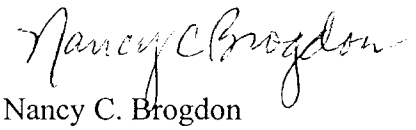
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Special 510(k) Number K023907

Device Name Cordis Maxi LD Large Diameter Balloon Dilatation Catheter

Indications for Use The Cordis Maxi LD Large Balloon Dilatation Catheter is intended for use in the dilatation of strictures of the esophagus.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023907